IN THE CLAIMS:

We Claim:

1. (withdrawn) An apparatus for dilating and delivering a medicament to an obstruction within a vascular segment or a body passageway which comprises:

a catheter having a distal end and a proximal end;

a substantially cylindrical shaped expansion member located on said distal end of said catheter, said expansion member having a first end and a second end, said first end being a distance from said second end;

B1 an altering means engagable to said first end and said second end of said expansion member for altering said first distance therebetween to move said expansion member between a first configuration wherein said expansion member is characterized by a first diameter and a second configuration wherein said expansion member is characterized by a second diameter, said second diameter being greater than said first diameter; and

a therapeutic agent or medicament coated on at least a portion of said expansion member.

2. (withdrawn) An apparatus as recited in claim 1 wherein said expansion member defines a flow passageway extending between said first end and said second end of the expansion member.

3. (withdrawn) An apparatus as recited in claim 1 wherein said expansion member comprises a first plurality of flexible elongate elements helically wound in a first direction of rotation and a second plurality of flexible elongate elements helically wound in a second direction of rotation to form a braid.

4. (withdrawn) An apparatus as recited in claim 1 wherein said expansion member is adapted to allow blood perfusion while said expansion member in either in said first diameter or in said second diameter.

5. (withdrawn) An apparatus as recited in claim 1 wherein said therapeutic agent or medicament is incorporated into a non-therapeutic substrate.

6. (withdrawn) An apparatus as recited in claim 1, wherein said therapeutic agent or medicament is an anticoagulant selected from the group consisting of D-Phe-Pro-Arg chloromethyl ketone, an RGD peptide-containing compound, heparin, an antithrombin compound, a platelet receptor antagonist, an anti-thrombin antibody, an anti-platelet receptor antibody, hirudin, hirulog, phe-pro-arg-chloromethyketone (Ppack), Factor VIIa, Factor Xa, aspirin, clopridogrel, ticlopidine, a prostaglandin inhibitor, a platelet inhibitor and a tick anti-platelet peptide, and combinations thereof.

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7. (withdrawn) An apparatus as recited in claim 1, wherein said therapeutic agent or medicament is a promoter of vascular cell growth selected from the group consisting of a growth factor stimulator, a growth factor receptor agonist, a transcriptional activator, and a translational promoter, and combinations thereof.

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8. (withdrawn) An apparatus as recited in claim 1, wherein said therapeutic agent or medicament is an inhibitor of vascular cell growth selected from the group consisting of a growth factor inhibitor, a growth factor receptor antagonist, a transcriptional repressor, a translational repressor, an antisense DNA, an antisense RNA, a replication inhibitor, an inhibitory antibody, an antibody directed against growth factors, a bifunctional molecule consisting of a growth factor and a cytotoxin, and a bifunctional molecule consisting of an antibody and a cytotoxin, double stranded DNA, single stranded DNA, single stranded RNA and a double stranded RNA and combinations thereof.

9. (withdrawn) An apparatus as recited in claim 1, wherein said therapeutic agent or medicament is selected from the group consisting of a cholesterol-lowering agent, a vasodilating agent, and agents which interfere with endogenous vasoactive mechanisms, estrogen, testosterone, steroid hormones, cortisol, dexamethasone, corticosteroids, thyroid hormones, thyroid hormones analogs, throid hormones antagonist, adrenocorticotrophic hormone, thyroid stimulating hormone, thyroid releasing factor, thyroid releasing factor analogs, thyroid releasing factor antagonists and combinations thereof.

10. (withdrawn) An apparatus as recited in claim 1, wherein said therapeutic agent or medicament is a smooth muscle inhibitor selected from the group consisting of an agent that modulates intracellular calcium binding proteins, a receptor blocker for contractile agonists, an inhibitor of the sodium/hydrogen antiporter, a protease inhibitor, a nitrovasodilator, a phosphodiesterase inhibitor, a phenothiazine, a growth factor receptor agonist, an anti-mitotic agent, an immunosuppressive agent, and a protein kinase inhibitor, and combinations thereof.

11. (withdrawn) An apparatus as recited in claim 1, wherein said therapeutic agent or medicament is a compound that inhibits cellular proliferation, Paclitaxel, Rapamycin, Sirolimus, Actinomycin D, Methotrexate, Doxorubicin, cyclophosphamide, and 5-fluorouracil, and combinations thereof.

12. (withdrawn) An apparatus as recited in claim 1 further comprising a plurality of therapeutic agents or medicaments coated on at least a portion of said expansion member.

13. (withdrawn) An apparatus as recited in claim 1, further comprising a lumen extending throughout the longitudinal length of said catheter, said lumen having a distal end that terminates within said expansion member, said lumen capable of delivering a medicament.

14. (withdrawn) An apparatus for dilating and delivering a medicament to an obstruction within a vascular segment or a body passageway which comprises:

a catheter having a distal end and a proximal end;

a substantially cylindrical shaped expansion member located on said distal end of said catheter, said expansion member having a first end and a second end, said first end being a distance from said second end;

an altering means engagable to said first end and said second end of said expansion member for altering said first distance therebetween to move said expansion member between a first configuration wherein said expansion member is characterized by a first diameter and a second configuration wherein said expansion member is characterized by a second diameter, said second diameter being greater than said first diameter;

one or more electrical leads extending throughout the longitudinal length of said catheter and engaged to said expansion member; and

a medicament coated on said expansion member.

15. (withdrawn) An apparatus as recited in claim 14 wherein said expansion member defines a flow passageway extending between said first end and said second end of the expansion member.

16. (withdrawn) An apparatus as recited in claim 14 wherein said expansion member comprises a first plurality of flexible elongate elements helically wound in a first direction of rotation and a second plurality of flexible elongate elements helically wound in a second direction of rotation to form a braid.

17. (withdrawn) An apparatus as recited in claim 14 wherein said expansion member is adapted to allow blood perfusion while said expansion member in either in said first diameter or in said second diameter.

18. (withdrawn) An apparatus as recited in claim 14 wherein said therapeutic agent or medicament is incorporated into a non- therapeutic substrate.

19. (withdrawn) An apparatus as recited in claim 14, wherein said therapeutic agent or medicament is an anticoagulant selected from the group consisting of D-Phe-Pro-Arg chloromethyl ketone, an RGD peptide-containing compound, heparin, an antithrombin compound, a platelet receptor antagonist, an anti-thrombin antibody, an anti-platelet receptor antibody, hirudin, hirulog, phe-pro-arg-chloromethyketone (Ppack), Factor VIIa, Factor Xa, aspirin, clopridogrel, ticlopidine, a prostaglandin inhibitor, a platelet inhibitor and a tick anti-platelet peptide, and combinations thereof.

20. (withdrawn) An apparatus as recited in claim 14, wherein said therapeutic agent or medicament is a promoter of vascular cell growth selected from the group consisting of a growth factor stimulator, a growth factor receptor agonist, a transcriptional activator, and a translational promoter, and combinations thereof.

21. (withdrawn) An apparatus as recited in claim 14, wherein said therapeutic agent or medicament is an inhibitor of vascular cell growth selected from the group consisting of a growth factor inhibitor, a growth factor receptor antagonist, a transcriptional repressor, a translational repressor, an antisense DNA, an antisense RNA, a replication inhibitor, an inhibitory antibody, an antibody directed against growth factors, a bifunctional molecule consisting of a growth factor and a cytotoxin, and a bifunctional molecule consisting of an antibody and a cytotoxin, double stranded DNA, single stranded DNA, single stranded RNA and a double stranded RNA and combinations thereof.

22. (withdrawn) An apparatus as recited in claim 14, wherein said therapeutic agent or medicament is selected from the group consisting of a cholesterol-lowering agent, a vasodilating agent, and agents which interfere with endogenous vasoactive mechanisms, estrogen, testosterone, steroid hormones, cortisol, dexamethasone, corticosteroids, thyroid hormones, thyroid hormones analogs, throid hormones antagonist, adrenocorticotrophic hormone, thyroid stimulating hormone, thyroid releasing factor,

thyroid releasing factor analogs, thyroid releasing factor antagonists and combinations thereof.

23. (withdrawn) An apparatus as recited in claim 14, wherein said therapeutic agent or medicament is a smooth muscle inhibitor selected from the group consisting of an agent that modulates intracellular calcium binding proteins, a receptor blocker for contractile agonists, an inhibitor of the sodium/hydrogen antiporter, a protease inhibitor, a nitrovasodilator, a phosphodiesterase inhibitor, a phenothiazine, a growth factor receptor agonist, an anti-mitotic agent, an immunosuppressive agent, and a protein kinase inhibitor, and combinations thereof.

24. (withdrawn) An apparatus as recited in claim 14, wherein said therapeutic agent or medicament is a compound that inhibits cellular proliferation, Paclitaxel, Rapamycin, Sirolimus, Actinomycin D, Methotrexate, Doxorubicin, cyclophosphamide, and 5-fluorouracil, and combinations thereof.

25. (withdrawn) An apparatus as recited in claim 14, further comprising a lumen extending throughout the longitudinal length of said catheter, said lumen having a distal end that terminates within said expansion member, said lumen capable of delivering a medicament.

26. (withdrawn) An apparatus as recited in claim 14, further comprising a plurality of therapeutic agents or medicaments coated on at least a portion of said expansion member.

27. (withdrawn) An apparatus as recited in claim 14, wherein said electrical leads can communicate electrical energy to said expansion member to compel said medicament or therapeutic agent into target tissues by iontophoretic means.

28. (withdrawn) An apparatus as recited in claim 14, wherein said electrical leads can communicate electrical energy to said expansion member to compel electroporation transfer of said medicament or therapeutic agent into target tissues.

29. (withdrawn) An apparatus as recited in claim 14, wherein said electrical leads can communicate electrical energy to said expansion member to cause both iontophoretic and electroporation transfer of said medicament or therapeutic agent into target tissues.

30. (withdrawn) An apparatus as recited in claim 14, wherein said electrical leads can communicate electrical energy to said expansion member to cause said medicament or therapeutic agent to electrically bond to said expansion member.

31. (currently amended) A mechanical dilatation and medicament delivery device comprising:

a catheter having a distal end, ~~and~~ a proximal end, <u>and an iontophoretic transport means,</u> said catheter having one or more lumens;

~~an expandable mesh~~ <u>a cylindrically shaped expansion member</u> positioned on said distal end of said catheter adapted to dilate an obstruction in a vessel, said cylindrically shaped expansion member mesh having a first contracted diameter and a second expanded diameter, said second expanded diameter being larger than said first contracted diameter; and

said mechanical dilatation and medicament delivery device being adapted to dilate said obstruction and expose said obstruction to a medicament <u>using said iontophoretic transport means</u> while allowing blood or bodily fluids to flow through said cylindrically shaped expansion member ~~expandable mesh~~.

32. (currently amended) A method for dilating and delivering a medicament to an obstruction in a body passageway which comprises the steps of:

advancing a mechanical dilatation catheter to a predetermined side ~~with~~ <u>within</u> a body

passageway, said catheter having a substantially cylindrical expansion member coated with a medicament and an iontophoretic transport means, said cylindrically shaped expansion member being moveable between a first contracted configuration wherein said expansion member is defined by a first dimension extending in a radial direction, and a second expanded configuration wherein said expansion member is defined by a second dimension extending in said radial direction;

applying a force on said cylindrically shaped ~~coated~~ expansion member in an axial direction to move said cylindrically shaped expansion member between said first contracted configuration to said second expanded configuration wherein said cylindrically shaped expansion member dilates said obstruction or body passageway and delivers the medicament to an said obstruction or body passageway using said iontophoretic transport means.

33. (original) A method as recited in claim 32 which further comprises the step of positioning a guidewire in the body passageway, and wherein said advancing step is accomplished by threading said expansion member over said guidewire.

34. (original) A method as recited in claim 32 which further comprises the step of allowing said expansion member to be in said second expanded configuration for a predetermined period of time after the dilatation step to further expose said obstruction to the medicament.

35. (currently amended) A method for dilating and delivering a medicament to an obstruction in a body passageway which comprises the steps of:

advancing a mechanical dilatation catheter to a predetermined site ~~with~~ within a body passageway, said catheter having ~~an~~ a cylindrically shaped expansion member coated with a medicament and ~~a~~ an iontophoretic transport means, said cylindrically shaped expansion member being moveable between a first contracted configuration wherein said member is defined by a first dimension extending in a radial direction, and a second expanded configuration wherein said expansion member is defined by a second dimension extending in said radial direction;

applying a force on said cylindrically shaped expansion member in an axial direction to move said expansion member between said first contracted configuration to said second expanded configuration wherein said obstruction is dilated; and

operating ~~supplying a flow of electrical current to~~ said iontophoretic means to deliver said medicament into said obstruction or body passageway.

36. (original) A method as recited in claim 35 which further comprises the step of positioning a guidewire in the body passageway, and wherein said advancing step is accomplished by threading said catheter over said guidewire.

37. (original) A method as recited in claim 35 which further comprises the step of allowing said expansion member to be in said second expanded configuration for a predetermined period of time after the dilatation step to further expose said obstruction to the medicament.

38. (original) A method as recited in claim 35 which further comprises the step of varying the electric current with time to provide a waveform that controls the rate of iontophoretic transport of said medicament.

39. (original) A method as recited in claim 35, further comprising, prior to advancing the catheter, the step of applying electrical energy to said expansion member to cause said medicament or therapeutic agent to electrically bond to said expansion member.

40. (withdrawn) A method for dilating and delivering a medicament to an obstruction in a body passageway which comprises the steps of:

advancing a mechanical dilatation catheter to a predetermined site with a body passageway, said catheter having an expansion member coated with a medicament and a electroporation transport means, said expansion member being moveable between a first contracted configuration wherein said member is defined by a first dimension extending in a radial direction, and a second expanded configuration wherein said member is defined by a second dimension extending in said radial direction;

applying a force on said expansion member in an axial direction to move said expansion member between said first contracted configuration to said second expanded configuration wherein said obstruction is dilated;

supplying a flow of electrical current to said electroporation means to deliver said medicament into said obstruction or body passageway.

41. (withdrawn) A method as recited in claim 40 which further comprises the step of positioning a guidewire in the body passageway, and wherein said advancing step is accomplished by threading said catheter over said guidewire.

42. (withdrawn) A method as recited in claim 40 which further comprises the step of allowing said expansion member to be in said second expanded configuration for a predetermined period of time after the dilatation step to further expose said obstruction to the medicament.

43. (withdrawn) A method as recited in claim 40 which further comprises the step of varying the electric current with time to provide a waveform that controls the rate of electroporation transport of said medicament.

44. (withdrawn) A method as recited in claim 40, further comprising, prior to advancing the catheter, the step of applying electrical energy to said expansion member to cause said medicament or therapeutic agent to electrically bond to said expansion member.

45. (new) An apparatus as recited in claim 31 wherein said cylindrically shaped expansion member comprises a first plurality of flexible elongate elements helically wound in a first direction of rotation and a second plurality of flexible elongate elements helically wound in a second direction of rotation to form a braid.

46. (new) An apparatus as recited in claim 31 wherein said expansion member is adapted to allow blood perfusion while said expansion member in either in said first diameter or in said second diameter.

47. (new) The apparatus as recited in claim 31, wherein the expansion member is coated with a combination of one or more medicaments and one or more polymers used to bond said medicaments to said expansion member.

48. (new) The apparatus as recited in claim 31, wherein the expansion member is coated with a medicament comprising an anticoagulant.

49. (new) The apparatus as recited in claim 31, wherein the expansion member is coated with a medicament selected from the group consisting of D-Phe-Pro-Arg chloromethyl ketone, an RGD peptide-containing compound, heparin, an antithrombin compound, a platelet receptor antagonist, an anti-thrombin antibody, an anti-platelet receptor antibody, hirudin, hirulog, phe-pro-arg-chloromethyketone (Ppack), Factor VIIa, Factor Xa, aspirin, clopridogrel, ticlopidine, a prostaglandin inhibitor, a platelet inhibitor and a tick anti-platelet peptide, and combinations thereof.

50. (new) The apparatus as recited in claim 31, wherein the expansion member is coated with a medicament comprising a promoter of vascular cell growth.

51. (new) The apparatus as recited in claim 31, wherein the expansion member is coated with a medicament selected from the group consisting of a growth factor stimulator, a growth factor receptor agonist, a transcriptional activator, and a translational promoter, and combinations thereof.

52. (new) The apparatus as recited in claim 31, wherein the expansion member is coated with a medicament comprising an inhibitor of vascular cell growth.

53. (new) The apparatus as recited in claim 31, wherein the expansion member is coated with a medicament selected from the group consisting of a growth factor inhibitor, a

growth factor receptor antagonist, a transcriptional repressor, a translational repressor, an antisense DNA, an antisense RNA, a replication inhibitor, an inhibitory antibody, an antibody directed against growth factors, a bifunctional molecule consisting of a growth factor and a cytotoxin, and a bifunctional molecule consisting of an antibody and a cytotoxin, double stranded DNA, single stranded DNA, single stranded RNA and a double stranded RNA and combinations thereof.

54. (new) The apparatus as recited in claim 31, wherein the expansion member is coated with a medicament comprising a cholesterol-lowering agent.

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55. (new) The apparatus as recited in claim 31, wherein the expansion member is coated with a medicament comprising a vasodilating agent.

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56. (new) The apparatus as recited in claim 31, wherein the expansion member is coated with a medicament comprising an agent that interferes with endogenous vasoactive mechanisms.

57. (new) The apparatus as recited in claim 31, wherein the expansion member is coated with a medicament selected from the group consisting of estrogen, testosterone, steroid hormones, cortisol, dexamethasone, corticosteroids, thyroid hormones, thyroid hormones analogs, throid hormones antagonist, adrenocorticotrophic hormone, thyroid stimulating hormone, thyroid releasing factor, thyroid releasing factor analogs, thyroid releasing factor antagonists and combinations thereof.

58. (new) The apparatus as recited in claim 31, wherein the expansion member is coated with a medicament comprising a smooth muscle inhibitor.

59. (new) The apparatus as recited in claim 31, wherein the expansion member is coated with a medicament comprising an agent that modulates intracellular calcium binding proteins.

60. (new) The apparatus as recited in claim 31, wherein the expansion member is coated with a medicament comprising a receptor blocker for contractile agonists.

61. (new) The apparatus as recited in claim 31, wherein the expansion member is coated with a medicament selected from the group consisting of an inhibitor of the sodium/hydrogen antiporter, a protease inhibitor, a nitrovasodilator, a phosphodiesterase inhibitor, a phenothiazine, a growth factor receptor agonist, an anti-mitotic agent, an immunosuppressive agent, and a protein kinase inhibitor, and combinations thereof.

62. (new) The apparatus as recited in claim 31, wherein the expansion member is coated with a medicament comprises a compound that inhibits cellular proliferation.

63. (new) The apparatus as recited in claim 31, wherein the expansion member is coated with a medicament selected from the group consisting of Paclitaxel, Rapamycin, Sirolimus, Actinomycin D, Methotrexate, Doxorubicin, cyclophosphamide, and 5-fluorouracil, and combinations thereof.

64. (new) A method as recited in claim 35 which further comprises the step of allowing said expansion member to be in said second expanded configuration for an indeterminate time period as necessary to delivery the medicament to the passageway.

65. (new) A method as recited in claim 35 which further comprises the step of varying the electric current with time to provide a square waveform that controls the rate of iontophoretic transport of said medicament.

66. (new) The method as recited in claim 35 wherein the passageway is a blood vessel.

67. (new) The method as recited in claim 35 further comprising the step operating the expandable member to dilate the passageway.

68. (new) The method as recited in claim 35, wherein the expansion member is coated with a combination of one or more medicaments and one or more polymers used to bond said medicaments to said expansion member.

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69. (new) The method as recited in claim 35, wherein the expansion member is coated with a medicament comprising an anticoagulant.

70. (new) The method as recited in claim 35, wherein the expansion member is coated with a medicament selected from the group consisting of D-Phe-Pro-Arg chloromethyl ketone, an RGD peptide-containing compound, heparin, an antithrombin compound, a platelet receptor antagonist, an anti-thrombin antibody, an anti-platelet receptor antibody, hirudin, hirulog, phe-pro-arg-chloromethyketone (Ppack), Factor VIIa, Factor Xa, aspirin, clopridogrel, ticlopidine, a prostaglandin inhibitor, a platelet inhibitor and a tick anti-platelet peptide, and combinations thereof.

71. (new) The method as recited in claim 35, wherein the expansion member is coated with a medicament comprising a promoter of vascular cell growth.

72. (new) The method as recited in claim 35, wherein the expansion member is coated with a medicament selected from the group consisting of a growth factor stimulator, a

growth factor receptor agonist, a transcriptional activator, and a translational promoter, and combinations thereof.

73. (new) The method as recited in claim 35, wherein the expansion member is coated with a medicament comprising an inhibitor of vascular cell growth.

74. (new) The method as recited in claim 35, wherein the expansion member is coated with a medicament selected from the group consisting of a growth factor inhibitor, a growth factor receptor antagonist, a transcriptional repressor, a translational repressor, an antisense DNA, an antisense RNA, a replication inhibitor, an inhibitory antibody, an antibody directed against growth factors, a bifunctional molecule consisting of a growth factor and a cytotoxin, and a bifunctional molecule consisting of an antibody and a cytotoxin, double stranded DNA, single stranded DNA, single stranded RNA and a double stranded RNA and combinations thereof.

75. (new) The method as recited in claim 35, wherein the expansion member is coated with a medicament comprising a cholesterol-lowering agent.

76. (new) The method as recited in claim 35, wherein the expansion member is coated with a medicament comprising a vasodilating agent.

77. (new) The method as recited in claim 35, wherein the expansion member is coated with a medicament comprising an agent that interferes with endogenous vasoactive mechanisms.

78. (new) The method as recited in claim 35, wherein the expansion member is coated with a medicament selected from the group consisting of estrogen, testosterone, steroid hormones, cortisol, dexamethasone, corticosteroids, thyroid hormones, thyroid

hormones analogs, throid hormones antagonist, adrenocorticotrophic hormone, thyroid stimulating hormone, thyroid releasing factor, thyroid releasing factor analogs, thyroid releasing factor antagonists and combinations thereof.

79. (new) The method as recited in claim 35, wherein the expansion member is coated with a medicament comprising a smooth muscle inhibitor.

80. (new) The method as recited in claim 35, wherein the expansion member is coated with a medicament comprising an agent that modulates intracellular calcium binding proteins.

81. (new) The method as recited in claim 35, wherein the expansion member is coated with a medicament comprising a receptor blocker for contractile agonists.

82. (new) The method as recited in claim 35, wherein the expansion member is coated with a medicament selected from the group consisting of an inhibitor of the sodium/hydrogen antiporter, a protease inhibitor, a nitrovasodilator, a phosphodiesterase inhibitor, a phenothiazine, a growth factor receptor agonist, an anti-mitotic agent, an immunosuppressive agent, and a protein kinase inhibitor, and combinations thereof.

83. (new) The method as recited in claim 35, wherein the expansion member is coated with a medicament comprises a compound that inhibits cellular proliferation.

84. (new) The method as recited in claim 35, wherein the expansion member is coated with a medicament selected from the group consisting of Paclitaxel, Rapamycin, Sirolimus, Actinomycin D, Methotrexate, Doxorubicin, cyclophosphamide, and 5-fluorouracil, and combinations thereof.

85. (new) The method as recited in claim 35 further comprising the step of providing the cylindrically shaped expansion member in the form of an expandable mesh.

86. (new) The method as recited in claim 35 further comprising the step of providing the cylindrically shaped expansion member having a perfusion passageway permitting fluid flow through the expansion member.

87. (new) The method as recited in claim 35 further comprising operating said iontophoretic means to supply a flow of electrical current to the cylindrically shaped expansion member.

88. (new) An apparatus for dilating and delivering a medicament to a passageway in the body, said apparatus comprising:

a catheter, said catheter characterized by a distal end adapted for insertion into the passageway for dilating a stenosis and delivering a medicament to said stenosis;

a cylindrically shaped expansion member disposed on the distal end of the catheter, said expansion member being moveable between a first contracted configuration wherein said expansion member is defined by a first dimension extending in a radial direction, and a second expanded configuration wherein said expansion member is defined by a second dimension extending in said radial direction;

said cylindrically shaped expansion member coated with a medicament subject to iontophoretic delivery; and

an iontophoretic transport means operably connected to the ~~expandable mesh~~ cylindrically shaped expansion member.